UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA	:	
-v-	:	23cr117 (DLC)
LAURA PERRYMAN,	:	OPINION AND ORDER
Defendant.	:	

APPEARANCES:

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DENISE COTE, District Judge:

The defendant has been charged in a three-count indictment with conspiracy, health care fraud, and securities fraud based on the defendant's alleged material misrepresentations about a component of a medical device. Trial is to begin on February

20. Following the exclusion the defendant's medical expert, Dr. David Spinner, the defendant was granted permission to file a supplemental report. The Government has renewed its motion to exclude Dr. Spinner's testimony. For the following reasons, the Government's motion is granted.

Background

The defendant, Laura Perryman, is the founder and former CEO of Stimwave Technologies Incorporated and Stimwave LLC (together, "Stimwave"). The defendant oversaw the design of the StimQ Peripheral Nerve Stimulation ("PNS") System (the "Device"), a medical device that treats chronic pain by producing electrical currents to target peripheral nerves, that is, the nerves outside the spinal cord. During the time at issue, the Device consisted of four components relevant to the indictment's charges: the Lead, the Battery, the Pink Stylet, and the White Stylet. The Lead is an implantable electrode array that stimulates the targeted nerve. The externally worn Battery provides power to the Lead. The Pink Stylet contains copper and is implanted into the body to function as an "antenna" and thereby to lengthen the transmission range of the Battery.

In its product materials for the Device, Stimwave identified both the Pink Stylet and the White Stylet as "receivers." When selling the Device to medical providers,

Perryman informed them that they could bill insurers for implanting the White Stylet as a receiver using CPT code 64590.[1] It is undisputed, however, that the White Stylet cannot function as a receiver; it has no copper.

On December 19, 2023, the Government filed a superseding indictment against the defendant, charging her with one count of conspiracy to commit health care fraud and wire fraud, one count of health care fraud, and one count of securities fraud. The Government and the defendant filed their respective motions in limine on January 12, 2024. Among the Government motions was a motion to exclude the testimony of Dr. Spinner. His expert report was attached to the Government's motion. The parties filed their opposition to these motions on January 19.

At a February 2 final pretrial conference, the Court excluded the testimony of Dr. Spinner pursuant to Fed. R. Evid. 401, 403, and 702. One of Dr. Spinner's opinions pertains to the functionality of the White Stylet. Dr. Spinner stated that the White Stylet served a medical purpose, namely that it helped prevent fluid ingress into the Lead. He added that it may also assist in preventing the collapse of the Lead's lumen. The Court held that Dr. Spinner's opinion as to the White Stylet's

[1] Current Procedural Terminology ("CPT") codes are used to track and bill medical, surgical, and diagnostic services. Medical insurers use CPT codes to determine how much money to pay medical providers.

functionality was inadmissible. Dr. Spinner's report did not provide a description of how he formed his opinion on functionality. His report did not detail his experience with the White Stylet or his basis for opining that it served a medical purpose. It was just the ipse dixit of the expert. He didn't describe any testing or experimentation with the White Stylet or any generally accepted view of the medical community. The Court also found that Dr. Spinner's opinion as to the White Stylet's potential for preventing collapse of the lumen was inadmissible speculation.

Dr. Spinner also opined that claims for reimbursement for implanting the Device could have been appropriately submitted to medical insurers using CPT code 64590 whether the White Stylet, the Pink Stylet, or no stylet was used with the StimQ PNS System. The Court noted that the jury needs to understand something about CPT codes because they were the mechanism through which medical providers were paid and were thereby able to cover the cost of the Device. It did not appear from his report, however, that Dr. Spinner was an expert on CPT codes. Dr. Spinner's opinion on CPT codes was given without any explanation for its basis. He failed to identify any sources or authorities on which his opinion was based, nor did he demonstrate that he has specialized knowledge as to the interpretation or application of CPT codes. The Court also

found that Dr. Spinner's opinion regarding CPT codes was irrelevant since it didn't confront the fact that Stimwave had sold the White Stylet by describing it as a receiver.

In light of the Court's ruling, the defendant requested leave to supplement Dr. Spinner's expert report. The Court granted this request, ordering the defendant to provide the supplemental report to the Government by February 6. The Court requested that the defendant point to any passage in the Stimwave materials that described the functionality of the White Stylet as Dr. Spinner did. The Government renewed its motion to exclude Dr. Spinner's testimony on February 9 and the defendant opposed that motion on February 12. This Opinion addresses the admissibility of the opinions offered by Dr. Spinner in the February 6 report.

Discussion

The Government has renewed its motion to exclude the testimony of Dr. Spinner, as described in the February 6 report, as unreliable, unsupported, irrelevant and unduly prejudicial. Dr. Spinner was given an opportunity to supplement his earlier report to demonstrate that the opinions he expressed in his initial report were sufficiently reliable to meet the requirements of Rule 702 and Daubert. This he has failed to do. In addition, he used the opportunity to add new opinions regarding CPT codes and the functionality of the White Stylet,

and an entirely new opinion regarding patient harm. Each of these new opinions is untimely and stricken on that ground alone. In addition, the defendant has failed to show that any of the opinions expressed in the February 6 report are admissible under Rule 702.

In an Order of February 1, the Court outlined the law to be applied to the motions in limine addressed at the final pretrial conference on the following day. For ease of reference, several of those legal principles are repeated here and additional evidentiary rules relevant to the issues raised by the parties in the discussion of Dr. Spinner's recent report are also described. Those legal standards pertain to Rules of Evidence 403, 702 and 703.

I. Legal Standards

A. Rule 403

Under Rule 403, courts may exclude relevant evidence "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. The term unfair prejudice refers "to the capacity of some concededly relevant evidence to lure the factfinder into declaring guilt on a ground different from proof specific to the offense charged." United States v. Massino, 546 F.3d 123, 132-33 (2d Cir. 2008) (citation omitted).

B. Rule 702

Federal Rule of Evidence 702 governs the admission of expert testimony. Rule 702 allows a "witness who is qualified as an expert by knowledge, skill, experience, training, or education" to testify, "in the form of an opinion or otherwise," if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Under this rule, the trial judge must first address "the threshold question of whether a witness is qualified as an expert by knowledge, skill, experience, training, or education to render his or her opinions." Nimely v. City of New York, 414 F.3d 381, 396 n.11 (2d Cir. 2005) (citation omitted).

If the trial judge finds the witness is qualified, she then has a "gatekeeper function," which requires her to ensure that any and all scientific testimony or evidence admitted "is not only relevant, but reliable." Restivo v. Hessemann, 846 F.3d 547, 575 (2d Cir. 2017) (citing Daubert v. Merrell Dow Pharms.,

Inc., 509 U.S. 579, 589 (1993)). Expert testimony is relevant where it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 265 (2d Cir. 2002) (citation omitted). To determine whether expert testimony has a sufficiently reliable foundation to be admissible at trial, a district court should consider the "indicia of reliability identified in [Rule] 702." Clerveaux v. E. Ramapo Central School Dist., 984 F.3d 213, 233 (2d Cir. 2021) (citation omitted). A district court may consider as well the Daubert factors in its assessment of the reliability of expert testimony. These factors include: "(1) whether the methodology or theory has been or can be tested; (2) whether the methodology or theory has been subjected to peer review and publication; (3) the methodology's error rate; and (4) whether the methodology or technique has gained general acceptance in the relevant scientific community." Id. (citing Daubert, 509 U.S. at 593-94).

The Daubert inquiry, however, is "fluid and will necessarily vary from case to case." In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II), 982 F.3d 113, 123 (2d Cir. 2020) (citation omitted). The gatekeeping inquiry must, of course, "be tied to the facts of a particular

case." United States v. Requena, 980 F.3d 30, 47 (2d Cir. 2020) (citation omitted).

"[T]here are many different kinds of experts, and many different kinds of expertise." United States v. Romano, 794 F.3d 317, 330 (2d Cir. 2015) (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999)). A court must "assess whether the expert employs the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Restivo, 846 F.3d at 577 (citation omitted). Expert testimony should be excluded "if it is speculative or conjectural or based on assumptions that are so unrealistic and contradictory as to suggest bad faith or to be in essence an apples and oranges comparison." Zerega Ave. Realty Corp. v. Hornbeck Offshore Transp., LLC, 571 F.3d 206, 214 (2d Cir. 2009) (citation omitted). Contentions that an expert's "assumptions are unfounded," however, "go to the weight, not the admissibility, of the testimony." Id. (citation omitted). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596.

To be admissible, an expert's analysis must be reliable "at every step." Amorgianos, 303 F.3d at 267. "[A]ny step that renders the analysis unreliable under the Daubert factors

renders the expert's testimony inadmissible." Id. (emphasis omitted). Moreover, "nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). "[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, Daubert and Rule 702 mandate the exclusion of that unreliable opinion testimony." Amorgianos, 303 F.3d at 266 (citation omitted).

"The role of an expert is not to displace the jury but rather to provide the groundwork to enable the jury to make its own informed determination." In re Methyl Tertiary Butyl Ether (MTBE) Products Liab. Litig., 725 F.3d 65, 114 (2d Cir. 2013) (citation omitted). Expert testimony assists the trier of fact "when it sheds light on activities not within the common knowledge of the average juror." United States v. Wexler, 522 F.3d 194, 204 (2d Cir. 2008) (citation omitted).

C. Rule 703

Rule 703 of the Federal Rules of Evidence allows an expert to present opinions derived from facts and data that are not otherwise admissible. It provides:

> An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would

> reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

Fed. R. Evid. 703.

"A district court has discretion under Federal Rule of Evidence 703 to determine whether the expert acted reasonably in making assumptions of fact upon which he would base his testimony." Electra v. 59 Murray Enterprises, Inc., 987 F.3d 233, 254 (2d Cir. 2021) (citation omitted).

> Although the Rules permit experts some leeway with respect to hearsay evidence, Fed. R. Evid. 703, a party cannot call an expert simply as a conduit for introducing hearsay under the guise that the testifying expert used the hearsay as the basis of his testimony.

Marvel Characters, Inc. v. Kirby, 726 F.3d 119, 136 (2d Cir. 2013) (citation omitted).

II. Dr. Spinner's Opinions

In his February 6 report, Dr. Spinner provides opinions addressed to three topics: CPT codes, the functionality of the White Stylet, and patient harm. Although he was allowed to file a supplemental report to provide support for the opinions he had timely disclosed to the Government, he has used this opportunity to add additional opinions as well. The opinions addressed to each of these three topics are inadmissible for the reasons described at the final pretrial conference and below.

A. CPT Codes

Dr. Spinner first opines in his February 6 report that CPT codes are "drafted in a manner that contemplates application to the medical procedure employed." He adds that CPT codes may be susceptible to "varying interpretation." Based on "[his] familiarity with the Device itself, and [his] familiarity with the procedure to implant neurostimulator devices to treat chronic pain", he opines that the procedure to permanently implant the StimQ PNS System "came within the plain language interpretation" of CPT code 64590. This was so when the provider "utilized" the White Stylet, the Pink Stylet, or no stylet "because the procedure always involved the insertion of a receiver." Dr. Spinner also explains his understanding of how CPT codes generally come to be drafted and why CPT code 64590 was revised in January 2024. He concludes that the revised CPT code 64590 and a new code that was created were "issued to cover new and innovative PNS devices such as the StimQ PNS System."[2]

Dr. Spinner's report does not provide a basis to find that he has any expertise in the drafting or revision of CPT codes. He is a physician who specializes in pain management. In giving his background he emphasizes the following. He is personally responsible for claims submitted to insurers when he has

[2] As noted above, the opinions offered for the first time in the February 6 report must also be excluded as untimely.

implanted PNS devices. He highlights a book for which he is the lead author that addresses the use of ultrasound techniques, which he explains are used to properly place neurostimulators implanted to treat peripheral nerve pain. He trains other physicians in PNS procedures. During that training he is frequently asked to give advice on CPT codes and "would typically advise that the prior version of CPT Code 64590 would be applicable prior to the release of new CPT codes in 2024."

Dr. Spinner also fails to show that he has acquired experience with implanting the White Stylet that qualifies him in opining on the use of CPT codes for that procedure. Dr. Spinner does not say that he ever implanted the White Stylet as a component of the StimQ PNS System. He does say that he "led trainings" on implanting the Device but does not say whether the White Stylet was a component of the Device at that point in time and whether his advice on CPT Codes addressed what code should be used in connection with a procedure that included implanting the White Stylet. He does not opine on facts that are at the heart of the Indictment's charges: that Perryman and her company told medical providers that the White Stylet was a receiver and that they could use CPT code 64590 to bill insurers for implanting it as a receiver.

In sum, the revised report does not cure the deficiencies that the Court highlighted at the February 2 conference. Thus,

Dr. Spinner's testimony on CPT codes is excluded under Rule 702 as beyond his areas of expertise, as unreliable and as irrelevant. Pursuant to Rule 403, it is excluded as creating an unacceptable risk of unfair prejudice and as highly likely to confuse the jury and distract their attention from the issues that they must resolve. These concerns far outweigh any minimal probative value from the testimony.

In her opposition to the Government's motion to preclude Dr. Spinner from testifying, the defendant does not suggest that Dr. Spinner has any expertise in CPT codes other than through his experience as a practitioner. She argues that, because it is the responsibility of the provider to determine which CPT code applies to their medical procedures, Dr. Spinner's experience as a provider qualifies him to serve as an expert. But Dr. Spinner's experience as a provider does not qualify him to opine on the drafting or revision of CPT codes. He is not involved in those processes and to the extent his February 6 report addresses those topics, it is beyond his area of expertise and inadmissible.

While the defendant has shown that Dr. Spinner is an experienced practitioner in the use of PNS devices, it bears repeating that his expert report remains silent as to his experience with the White Stylet. He does not explain whether he has ever personally implanted the White Stylet or trained

others to do so, or whether he has ever had to decide in either context which CPT code should he used to bill for a procedure in which the White Stylet is implanted. Nor does the fact that he has experience selecting CPT codes when implanting PNS devices make him an expert in CPT codes. Nor does the fact that he may be asked and choose to answer questions about CPT codes when training others how to implant a PNS device make him an expert on the codes. These deficiencies are directly relevant to whether he is qualified to serve as an expert regarding CPT codes in general and more specifically as an expert on CPT codes that will are relevant to the issues here.

B. Functionality of the White Stylet

Dr. Spinner next opines that the White Stylet served "a number of medical functions." He does not discuss whether it could serve as a receiver. He opines instead that it performed three other functions.[3] It "filled the inner lumen, thereby helping to prevent fluid ingress into the stimulator receiver and electrode array, which could result in a loss of function and heightened risk of infection or other collateral complications." He adds that it "would also assist in preventing the collapse of the" lumen and in "stabilizing and providing additional rigidity to stimulator receiver."

[3] Two of these three opinions must be excluded as untimely.

Dr. Spinner's opinion regarding the functionality of the White Stylet is excluded under Rules 702 and 403. Dr. Spinner has provided no basis to find that this testimony constitutes a reliable expert opinion as required by Rule 702 and Daubert. Any probative value, which is minimal, is substantially outweighed by the risks of confusion, misleading the jury, and unnecessarily prolonging the trial.

Dr. Spinner does not explain the basis for his opinions regarding functionality. He does not refer to any testing that supports these opinions of the need to use the White Stylet, which was sold as a receiver, to perform entirely separate functions. He does not point to any company-issued literature that describes any of these separate functions as necessary to the success of its electrode array or as reasons for implanting the White Stylet. This absence is striking since, during the February 2 conference, the Court requested that the defendant identify any company-issued literature regarding this functionality. He does not even describe his own experience with the White Stylet, for example to explain why he found it necessary to implant the White Stylet even though he understood it was not a receiver. There is simply no support or explanation given to allow a finding that these opinions on functionality rest on a reliable basis or are anything other than Dr. Spinner's pronouncements.

The two documents to which Dr. Spinner cites do not fill this gap. One is a document co-authored by the defendant. While the defendant will be given an opportunity at trial to explain her understanding of functionality, an expert cannot be a substitute for that testimony. Fed. R. Evid. 704(b). In any event, Dr. Spinner does not quote any passage explaining that the stylet assists the functionality of the Lead by sealing the lumen, preventing the lumen's collapse, or stabilizing the Lead. His citation to a book regarding pacemakers is similarly vague.

Nor is Dr. Spinner's testimony salvaged by his observation that he is unaware of any study suggesting that leaving an implantable device "open" in the body is "desirable or beneficial". He adds that there is no PNS device on the market that leaves the device "open". But Dr. Spinner does not explain how the White Stylet prevents fluid ingress into the lumen, does not describe any testing to confirm that the White Stylet succeeds in that function, nor does he compare its success in doing so with any other solution for that issue. His testimony, again, is simply a bald, unsupported statement of opinion.

In her opposition to the Government's motion, the defendant argues that Dr. Spinner's expert opinion is reliable because it is based on his professional experience. But again, Dr. Spinner does not describe any professional experience with the White Stylet, the functions it has served when he implanted the

Device, and how he knows that the White Stylet has in fact prevented fluid from entering the Lead. In fact, Dr. Spinner does not state that he ever implanted the Device during the years when it was sold with the White Stylet. Dr. Spinner also does not state that he described the functionality of the White Stylet during the training sessions he conducted on PNS devices. Therefore, even if use of the White Stylet in his own practice would be sufficient to find Dr. Spinner an expert on its functionality, his expert report does not describe that use. His testimony is not sufficiently reliable to meet the Rule 702 standard.

Finally, the defendant asserts that Dr. Spinner's testimony is supported by a learned treatise, specifically the publication that the defendant co-authored in 2015. See Fed. R. Evid. 803(18). The authoritativeness of a study, and its admissibility into evidence, may be adequately established through the testimony of an expert witness. Caruolo v. John Crane, Inc., 226 F.3d 46, 55 (2d Cir. 2000). Dr. Spinner, however, fails to explain why this article is trustworthy or authoritative. While defense counsel provides citation to that article, nothing in that article addresses the role of a stylet in preventing fluid from entering the lumen of the Lead, preventing the collapse of the lumen or stabilizing the Lead. The only function of the antenna that is discussed is its

function as a receiver. To wit, "[t]he deeper a device antenna is placed in tissue, the longer the antenna must be to receive sufficient power from the emitted microwave frequencies due to the wavelength of the electromagnetic energy." The article that the defendant co-authored does not, therefore, provide a basis to find that Dr. Spinner's opinion about the functionality of the White Stylet is supported by a learned treatise or is otherwise sufficiently reliable to be presented to a jury.

C. Patient Harm

Finally, Dr. Spinner adds new opinions on the topic of patient harm that were not included in his initial report. He says that he is unaware "of any indication" that use of the White Stylet "caused patient harm". He adds that it is "highly unlikely" in his experience that its use would be the cause of any "actual patient harm."

These opinions are untimely. His expert report was due January 5 and these opinions were not included in that report. They are therefore excluded on that basis alone. The defendant has also failed to show that Dr. Spinner's testimony regarding patient harm is admissible evidence.

In any event, it appears that the reason for proffering these opinions no longer exists. The defendant feared that the Government would offer evidence at trial that use of the White Stylet had caused patient harm. For this reason, one of her

motions in limine requested that the Government be precluded from introducing such evidence. The Court required the parties to confer regarding the issue. In a letter of February 13, the Government represents that it will not offer evidence of patient harm unless "the defense opens the door to the question of patient harm or benefit."

D. Rebuttal of Government Experts

The defendant argues that she has a right to rebut the Government's experts and that the exclusion of Dr. Spinner's testimony will deprive her of a fair trial. She points out that Dr. Spinner is a recognized expert in PNS procedures. These arguments do not confront the legal impediments to the admission of testimony by Dr. Spinner. His proffered testimony is inadmissible under the well established legal standards recited above. The Rules of Evidence play an essential role in protecting a party's right to a fair trial and the defendant will be allowed to offer evidence and confront the Government's evidence to the extent permitted by those rules.

Conclusion

The Government's renewed motion in limine of February 9 to exclude the expert testimony of Dr. Spinner is granted.

Dated: New York, New York
February 15, 2024

DENISE COTE
United States District Judge